Evaluating the impact of introducing standardized packaging with larger health-warning labels in England: findings from adult smokers within the EUREST-PLUS Europe Surveys

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Background: The European (EU) Tobacco Product Directive (TPD) was implemented in May 2016 to regulate the design and labelling of cigarettes and roll-your-own tobacco. At the same time, the UK introduced standardized packaging measures, whereas Germany, Greece, Hungary, Poland, Romania and Spain did not. This study examines the impact of introducing standardized packaging in England using a quasi-experimental design.

Methods: Data from adult smokers in Waves 1 (2016; N=9547) and 2 (2018; N=9724) from the International Tobacco Control Policy Evaluation surveys (England) and EUREST-PLUS surveys (Germany, Greece, Hungary, Poland, Romania and Spain) were used. Generalized estimating equations were used to estimate changes in pack/brand appeal, salience of health-warning labels (HWLs) and perceived relative harm of different brands in England (where larger HWLs and standardized packaging were implemented), vs. each EU country (where only larger HWLs were implemented). Results: There was an increase in the percentage of respondents from Germany, Hungary and Poland reporting they did not like the look of the pack (4.7%, 9.6%, and 14.2%, respectively), but the largest increase was in England (41.0%). Moreover, there was a statistically significant increase in the salience of HWLs in Hungary, Poland and Romania (17.0%, 13.9%, and 15.3%, respectively), but the largest increase was in England (27.6%). Few differences were observed in cross-country comparisons...
Background

Over the last few decades, many countries have imposed restrictions on tobacco marketing through bans on advertising on television, radio, billboards and point-of-sale displays. Branded packaging represents one of the last remaining channels for tobacco advertising among countries with comprehensive marketing bans. The tobacco industry uses pack design elements, such as the colour of cigarette packs, to distinguish brands, promote specific brand imagery and target specific sub-groups. To counter this form of advertising, standardized packaging has been recommended in the WHO Framework Convention for Tobacco Control (FCTC) guidelines under Articles 11 and 13 to reduce the appeal of tobacco products, increase the noticeability and effectiveness of health warnings (HWLs) and reduce the use of packaging design to mislead consumers into believing that some products are less harmful than others.

In England, standardized packaging was introduced in May 2016, requiring cigarettes and rolling tobacco to be sold in brown-coloured packaging. At the same time, new measures were introduced under the European (EU) Tobacco Products Directive (TPD) that required larger, combined text and graphic HWLs on packaging, covering 65% of the front and the back of cigarette and roll-your-own tobacco packs and included a ban on promotional and misleading elements on tobacco products, thus, leading to a unique opportunity to assess the two policies. Systematic reviews indicate that standardized packaging reduces the appeal of tobacco products. For instance, studies have demonstrated that cigarettes in standardized packs are perceived to be of lower quality, compared to branded packs. Studies have also shown that standardized packs increase the noticeability of HWLs, compared to branded packs; with respect to HWLs, those that were larger and included pictorial health warnings were found to be more effective than smaller text-based messages. A recent review examining the impact of standardized packaging on the perceived relative harm of different brands showed mixed findings. Studies indicate that factors, such as the presence of descriptors (e.g. smooth, gold), may play a role in shaping harm perceptions; these factors may explain the discrepancies observed in previous studies. Given that standardized packaging does not restrict the use of descriptors, the tobacco industry is still able to use descriptors as a way of misleading consumers into thinking that some brands are less harmful than others.

Though reviews to date have shown that standardized packaging may increase the salience of HWLs and reduce pack appeal, one key limitation of studies to date is that they do not account for the confounding effects of concurrently introducing larger HWLs. In all published studies to date, standardized packaging has been implemented at the same time as larger HWLs. As such, it has not been possible to separate the effects of larger HWLs from standardized packaging. As more countries adopt standardized packaging, evaluations of natural experiments comparing jurisdictions that introduce only HWLs vs. combined policies (i.e. HWLs and standardized packaging) may offer timely evidence that addresses this limitation.

The distinct policies implemented relating to standardized packaging in Europe along with the EU-wide implementation of larger HWLs under the TPD offer a unique opportunity to evaluate its impact within the context of a natural experiment. The primary objective of this study was to evaluate the impact of introducing larger HWLs and standardized packaging in England against the impact of only introducing larger HWLs in Germany, Greece, Hungary, Poland, Romania and Spain. Specifically, the study examined the impact of standardized packaging on perceptions of (i) pack/brand appeal; (ii) salience of HWLs; and (iii) relative harms of different brands. We hypothesized that standardized packaging would reduce pack appeal, enhance the salience of HWLs and reduce misperceptions of harm associated with different brands.

Methods

Design

The International Tobacco Control Policy Evaluation (ITC) Project is a prospective cohort study designed to investigate the psychosocial and behavioural effects of tobacco control policies, at national and international levels. This study used data from seven participating EU countries. Longitudinal data from Germany, Greece, Hungary, Poland, Romania and Spain were derived from Wave 1 (2016) and 2 (2018) of the ITC 6 E Countries (6E) survey, as part of the Horizon 2020-funded project European Regulatory Science on Tobacco: Policy implementation to reduce lung diseases (EUREST-PLUS). The ITC 6E survey was designed to evaluate the impact of the implementation of the TPD and FCTC policies in the EU. Longitudinal data from England were derived from Wave 1 (2016) and 2 (2018) of the England arm of the ITC Four Country Smoking and Vaping (4CV) Survey.

Data from the England arm of the ITC 4CV Survey were collected through face-to-face interviews conducted using computer-assisted personal interviews. Interviews were conducted with adults aged 18+ years who smoked at least monthly and had smoked at least 100 cigarettes in their lifetime. The sampling design used geographic strata defined by Nomenclature of Territorial Units for Statistics regions crossed with degree of urbanization (urban, intermediate and rural). Approximately 100 clusters were sampled within each country; within each cluster, 10 adult smokers were interviewed. In each cluster, interviewers utilized a random-walk design in the selection of household addresses to approach. From each household sampled, one male and one female smoker were selected for an interview, where possible. The screening process continued until the required number of smokers from each stratum was reached.

Waves 1 and 2 of the England arm of the ITC 4CV Survey were conducted from June to September 2016 and February to May 2018, respectively. The retention rates of both waves were ~70% in Germany and Spain but ranged from 36% to 55% in other 6E countries, resulting in the use of replenishment samples at Wave 2.

Data from the ITC England Survey were collected online using probability-based sampling frames, non-probability opt-in panels or a combination of both. The sample was comprised of individuals aged 18+ and included: (i) re-contacted smokers and quitters who had participated in previous waves of the study; (ii) newly recruited current smokers and recent quitters (quit ≤2 years); and (iii) newly recruited e-cigarette users who reported at least weekly use. Waves 1 and 2 of the ITC England Survey were conducted from July to September 2016 and February to July 2018, respectively. The retention rates between both waves were ~39%; as such, replenishment samples were used at Wave 2.

Additional details regarding the survey methodology used can be found elsewhere. The analytic sample consisted of adult smokers that participated at Waves 1 (N = 9547) and 2 (N = 9724) of the
EUREST-PLUS and England arm of the ITC 4CV. These surveys will be collectively referred to as the EUREST-PLUS ITC Europe Surveys. Sample characteristics at both waves are provided in Supplementary Table S1.

Measures
Demographics and smoking-related measures
Respondents were asked to report their gender (male or female), age group (18–24, 25–39, 40–54, 55+), education (low, moderate, high) and household income (low, moderate, high and not reported). A separate variable was created to identify respondents' country of residence (England, Germany, Greece, Hungary, Poland, Romania and Spain).

Nicotine dependence was measured using the Heaviness of Smoking Index (HSI). HSI was calculated as the sum of two categorical measures: number of cigarettes smoked per day and time to first cigarette of the day. Consistent with previous research, Nicotine dependence was measured using the Heaviness of Smoking Index (HSI). HSI was calculated as the sum of two categorical measures: number of cigarettes smoked per day and time to first cigarette of the day. Consistent with previous research, HSI scores between 0 and 1 were classified as low, 2 and 3 as moderate and 4 and 6 as high nicotine dependence. Respondents were asked to report whether they had made an attempt to quit smoking within the past year (yes/no).

Outcome variables
Pack/brand appeal: respondents were asked, 'To what extent do you like the look of your cigarette pack?' Consistent with previous research, response options were dichotomized into 'not at all' vs. otherwise (i.e. 'a little/somewhat/quite a lot/very much/I don't know'). Respondents were also asked, 'Now, thinking about the quality of your cigarettes, would you describe them as: very high quality, high quality, medium quality or low quality?' As in previous work, response options were dichotomized into 'very high/high' vs. otherwise (i.e. 'medium/low quality/I don't know'). Respondents were asked, 'How much do brands differ in terms of how prestigious they are?' Response options were dichotomized into 'a little/some-what/very different' vs. otherwise (i.e. 'not at all/I don't know').

Salience of HWLs: respondents were asked, 'When you look at a cigarette pack, what do you usually notice first—the warning labels, or other aspects of the pack, such as branding?' Responses were dichotomized into 'warning labels' vs. otherwise (i.e. 'other aspects of the pack/I don't know').

Perceived relative harm of different brands: respondents were asked, 'Based on your experience of smoking, do you think that [your usual brand/the brand you are currently smoking] might be a little less harmful, no different, or a little more harmful, compared to other cigarette brands?' Consistent with previous research, response options were dichotomized into 'no different' vs. otherwise (i.e. 'a little less/a little more/I don't know'). Respondents were also asked, 'Is your brand harsher or smoother on your throat compared to other brands?' Response options were dichotomized into 'about the same' vs. otherwise (i.e. 'harsher/smacker/I don't know').

Analysis
Descriptive statistics were used to examine demographic and smoking-related characteristics at Waves 1 (2016) and 2 (2018) for the unweighted sample. To address our main research objective, weighted logistic generalized estimating equations (GEE) regression models were used to test changes in perceptions of pack/brand appeal, salience of HWLs and relative harm of different brands in each country between Waves 1 and 2. Logistic GEE models were also used to evaluate the impact of standardized packaging introduced within England on these changes, relative to each of the 6E countries (where standardized packaging was not implemented). This was done by testing the interaction between country and wave for each outcome measure. GEE models accounted for the survey sampling design, sampling weights and use of repeated measures. GEE models controlled for gender, age, household income, education, nicotine dependence, quit attempts and wave of recruitment. Descriptive analyses were conducted using SAS 9.4, whereas GEE models were estimated using SAS-callable SUDAAN Version 11.0.3.

Results
Pack/brand appeal
There was an increase from Wave 1 to 2 in the percentage of respondents from Germany, Hungary and Poland that reported not liking the look of the pack, after adjusting for demographics and smoking-related behaviours (4.7%, 9.6% and 14.2%, respectively); the largest increase was observed in England (41.0%). Between-country comparisons showed that the change from Wave 1 to 2 was greater in England than in each of the six countries (Table 2, all \( P < 0.05 \)). Among respondents from England, there was an increase in reporting that the quality of their cigarettes was high/very high from Wave 1 to 2 (\( P = 0.013 \); Table 1). There was a decrease in reporting that brands differed in prestige among respondents from England (\( P = 0.01; \) Table 1); similar findings were also observed in Romania (\( P = 0.013 \); Table 1).

Salience of HWLs
Among respondents from Hungary, Poland and Romania, there was an increase in the percentage of respondents reporting they usually noticed HWLs first before other aspects of the pack, after adjusting for demographics and smoking-related behaviours (17.0%, 13.9% and 15.3%, respectively); the largest increase was observed in England (27.6%) (Table 1). Between-country comparisons showed that the increase in England was greater than the change in each of the six countries (Table 2, all \( P < 0.05 \)).

Relative harm of different brands
Among respondents from Romania, there was a decrease from Wave 1 to 2 in reporting that one's own brand was no different in harmfulness compared to other brands, adjusting for demographics and smoking-related behaviours (\( P = 0.015 \); Table 1). However, no significant changes were observed in other countries (Table 1). Findings showed a decrease in reporting that one's own brand was no different in harshness than other brands among respondents from Romania (\( P = 0.028 \); Table 1). However, there was an increase in the percentage of respondents from Spain reporting that one's own brand was no different in harshness than other brands from Wave 1 to 2 (\( P = 0.001; \) Table 1). The change in perceived relative harm of one's own brand in England was significantly different than the change in Romania (aOR = 1.42). However, the change in England was not significantly different than the change in each of the other five countries. With respect to perceived relative harshness, there was a small increase in England and this change differed significantly from the decreases observed in Romania and Poland (aOR = 1.48 and 1.46, respectively; Table 2).

Discussion
This is the first study to date to evaluate the impact of standardized packaging separately from larger HWLs using a rigorous quasi-experimental design. Findings showed that standardized packaging measures introduced in England were effective in reducing pack appeal and increasing salience of HWLs. Standardized packaging did appear to have some effect in correcting perceptions of harm associated with different brands; respondents from England had small increases in perceptions that their own brand did not differ in harshness, compared to Romania and Poland (where decreases were observed). These effects were not observed in any other cross-country comparisons.
Country-specific findings showed an increase in the salience of HWLs in England, Poland, Hungary and Romania post-TPD. As predicted, country comparisons showed that respondents from England had more pronounced increases in salience relative to each of the 6E countries (where standardized packaging was not implemented). These findings reinforce previous research demonstrating that standardized packaging increases the noticeability of HWLs.\textsuperscript{12-14}

As predicted, the largest changes in pack appeal were observed within England, whereby the change in percentage of respondents reporting they did not like the look of the pack was much greater in England than in other countries. This finding suggests that standardized packaging had an added positive effect of reducing pack appeal over and above increasing the size of the HWLs. Findings also showed reductions in pack appeal in Germany, Hungary and Poland post-TPD; however, the degree of change in pack appeal varied by country. Country differences are likely attributable to baseline differences (i.e. the pre-TPD regulatory context) within each country. For instance, pre- to post-TPD, some countries moved from text-only to pictorial HWLs, whereas others already had pictorial HWLs in effect pre-TPD (Supplementary table S2).

Table 1 Results of GEE models testing changes in perceptions of pack/brand appeal, salience of HWLs and perceptions of relative harm of different brands within each country between Waves 1 and 2 among respondents of the EUREST-PLUS ITC Europe Surveys

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>Germany</th>
<th>Greece</th>
<th>Hungary</th>
<th>Poland</th>
<th>Romania</th>
<th>Spain</th>
<th>England</th>
</tr>
</thead>
<tbody>
<tr>
<td>W1 (%)</td>
<td>W2 (%)</td>
<td>% diff.*</td>
<td>W1 (%)</td>
<td>W2 (%)</td>
<td>% diff.*</td>
<td>W1 (%)</td>
<td>W2 (%)</td>
</tr>
<tr>
<td>Pack appeal (no. of observations: N =16 949; no. of individuals: N =13 434\textsuperscript{b})</td>
<td>7.6</td>
<td>12.3</td>
<td>4.7**</td>
<td>9.3</td>
<td>13.6</td>
<td>4.3</td>
<td>5.1</td>
</tr>
<tr>
<td>Do not like the look of the pack at all</td>
<td>18.3</td>
<td>15.5</td>
<td>−2.8</td>
<td>13.9</td>
<td>54.9</td>
<td>41***</td>
<td></td>
</tr>
<tr>
<td>Brand appeal (no. of observations: N =16 973; no. of individuals: N =13 449\textsuperscript{b})</td>
<td>30.3</td>
<td>27.3</td>
<td>−3</td>
<td>25.7</td>
<td>23.3</td>
<td>−2.4</td>
<td>24.2</td>
</tr>
<tr>
<td>Quality of their cigs is high/very high</td>
<td>57.5</td>
<td>62.3</td>
<td>4.8</td>
<td>34.8</td>
<td>38.9</td>
<td>4.1*</td>
<td></td>
</tr>
<tr>
<td>Brand appeal (no. of observations: N =16 970; no. of individuals: N =13 445\textsuperscript{b})</td>
<td>88.4</td>
<td>86.6</td>
<td>−1.8</td>
<td>94.4</td>
<td>94</td>
<td>−0.4</td>
<td>98.6</td>
</tr>
<tr>
<td>Brands differ in prestige</td>
<td>94.3</td>
<td>90.3</td>
<td>−4*</td>
<td>91.4</td>
<td>91.5</td>
<td>0.1</td>
<td>87.1</td>
</tr>
<tr>
<td>Salience of HWLs (no. of observations: N =17 637; no. of individuals: N =13 992\textsuperscript{b})</td>
<td>13.4</td>
<td>12.8</td>
<td>−0.6</td>
<td>9.8</td>
<td>15.1</td>
<td>5.3</td>
<td>29</td>
</tr>
<tr>
<td>Notice HWLs first</td>
<td>20.2</td>
<td>23.9</td>
<td>3.3</td>
<td>18.3</td>
<td>45.9</td>
<td>27.6***</td>
<td></td>
</tr>
<tr>
<td>Relative harm of different brands (no. of observations: N =16 969; no. of individuals: N =13 446\textsuperscript{b})</td>
<td>85.1</td>
<td>81.8</td>
<td>−3.3</td>
<td>86.9</td>
<td>88.2</td>
<td>1.3</td>
<td>77</td>
</tr>
<tr>
<td>Their own brand is no different in harm</td>
<td>71.7</td>
<td>64.8</td>
<td>−6.9*</td>
<td>82.4</td>
<td>85.5</td>
<td>3.1</td>
<td>78.1</td>
</tr>
<tr>
<td>Relative harshness of different brands (no. of observations: N =16 972; no. of individuals: N =13 448\textsuperscript{b})</td>
<td>55.4</td>
<td>59.6</td>
<td>4.2</td>
<td>38.2</td>
<td>40.8</td>
<td>2.6</td>
<td>63.8</td>
</tr>
<tr>
<td>Their own brand is no different in harshness</td>
<td>55.5</td>
<td>48.3</td>
<td>−7.2*</td>
<td>52.8</td>
<td>70</td>
<td>17.2***</td>
<td></td>
</tr>
</tbody>
</table>

Note: The weighted estimates shown above are based on the results of a logistic regression model estimated using GEE, adjusting for gender, age, household income, education, wave of recruitment, nicotine dependence (HSI) and past-year quit attempts. Estimates shown in bold type are significant at \( P<0.05 \).
a: Absolute percent difference.
b: Number of observations refers to the total number of observations each respondent contributes to the model and number of individuals refers to the number of unique respondents present in the model.
* : \( P<0.05 \);
** : \( P<0.01 \);
*** : \( P<0.001 \).

For the most part, the degree of change in pack appeal across countries appears to reflect the extent of changes to the pack design brought on by the TPD (in all seven countries) and standardized packaging (in England). Other country-level factors (e.g. prevalence of tobacco use, cultural differences) may also play a role in explaining cross-country differences.

Contrary to initial hypotheses, the extent of changes in perceptions of brand prestige and cigarette quality did not differ between England and each of the 6E countries. These findings were inconsistent with previous evaluations of standardized packaging.\textsuperscript{13,15} It is worth noting that previous evidence is largely derived from Australian studies, where there were some notable differences in the implementation of standardized packaging. Specifically, the roll-out period for standardized packaging in Australia was much shorter than that in the UK (2 months vs. 12 months),\textsuperscript{29} this may partially explain the discrepancy in results. These inconsistencies may have also been generated by differences in study design of previous research (i.e. use of experimental, rather than real-world settings). Moving forward, future research is needed to evaluate the longer-term impact of standardized packaging on these outcome measures.
With respect to the impact of standardized packaging on perceptions of the relative harshness of different brands, our study showed mixed findings. The changes observed in England were not significantly different from changes in Hungary, Greece and Germany. Interestingly, respondents from Spain (where standardized packaging was not in effect) had larger increases in reporting that brands do not differ in harshness over time (i.e. from Wave 1 to 2), relative to changes in England. These findings may reflect the strength of tobacco control policies in effect in each country (Supplementary Table S3). Spain has a higher score on the Tobacco Control Scale (TCS) relative to other EU countries, including Poland, Greece and Germany; a higher score on the TCS indicates stronger tobacco control policies are in effect.\textsuperscript{29} The discrepancy in findings may also be a function of other factors. Studies have shown that the use of brand descriptors has been found to mislead consumers about the harmfulness of tobacco products\textsuperscript{52}; standardized packaging measures introduced in England did not include restrictions on the use of descriptors. It may be the case that the presence of brand descriptors reduced the impact of standardized packaging on the perceived relative harm of different brands.

Our findings have important implications at a time when many countries are tabling or introducing standardized packaging. This study offers timely evidence that incorporating standardized packaging into the use of descriptors may help to reduce the appeal of the pack and enhance the noticeability of HWLs over and above the effects of introducing HWLs only. These findings lend support for the incorporation of standardized packaging measures into the EU TPD.

**Conclusions**

This study represents the first evaluation to date to separate the effects of introducing standardized packaging measures from introducing larger pictorial HWLs only. Study findings suggest that standardized packaging reduces the appeal of the pack and enhances the noticeability of HWLs over and above the effects of introducing HWLs only. These findings lend support for the incorporation of standardized packaging measures into the EU TPD.

**Supplementary data**

Supplementary data are available at EURPUB online.

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**Table 2** Results of GEE models testing the country by wave interaction effect for outcomes measures relating to pack/brand appeal, salience of HWLs and perceptions of relative harm of different brands among respondents of the EUREST-PLUS ITC Europe Surveys

<table>
<thead>
<tr>
<th>Perceptions of pack and brand appeal</th>
<th>Perceptions of salience of HWLs</th>
<th>Perceptions of harm/harshness of brands</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not like the look of the pack at all vs. otherwise</td>
<td>Quality of their ciggs is high/very high vs. otherwise</td>
<td>Notices HWLs first vs. otherwise</td>
</tr>
<tr>
<td>No. of observations: 16 949&lt;sup&gt;a&lt;/sup&gt;</td>
<td>No. of observations: 16 973&lt;sup&gt;b&lt;/sup&gt;</td>
<td>No. of observations: 17 637&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>No. of individuals: 13 449&lt;sup&gt;d&lt;/sup&gt;</td>
<td>No. of individuals: 13 449&lt;sup&gt;d&lt;/sup&gt;</td>
<td>No. of individuals: 13 449&lt;sup&gt;d&lt;/sup&gt;</td>
</tr>
<tr>
<td>aOR (95% CI)&lt;sup&gt;e&lt;/sup&gt;</td>
<td>aOR (95% CI)&lt;sup&gt;e&lt;/sup&gt;</td>
<td>aOR (95% CI)&lt;sup&gt;e&lt;/sup&gt;</td>
</tr>
<tr>
<td>England vs. Poland</td>
<td>2.31 (1.31–4.07)</td>
<td>2.09 (1.39–3.14)</td>
</tr>
<tr>
<td>England vs. Hungary</td>
<td>2.37 (1.37–4.10)</td>
<td>1.82 (1.25–2.66)</td>
</tr>
<tr>
<td>England vs. Greece</td>
<td>4.95 (2.83–8.69)</td>
<td>2.34 (1.26–4.36)</td>
</tr>
<tr>
<td>England vs. Germany</td>
<td>4.50 (3.05–6.67)</td>
<td>4.04 (2.70–6.03)</td>
</tr>
</tbody>
</table>

Changes over time by country interaction<sup>f</sup>

England vs. Romania | 6.06 (4.21–8.73) |
England vs. Spain | 9.45 (6.43–13.89) |
England vs. Poland | 2.31 (1.31–4.07) |
England vs. Hungary | 2.37 (1.37–4.10) |
England vs. Greece | 4.95 (2.83–8.69) |
England vs. Germany | 4.50 (3.05–6.67) |

| a: Number of observations refers to the total number of observations each respondent contributes to the model. |
| b: Number of individuals refers to the number of unique respondents present in the model. |
| c: aOR, adjusted odds ratio; 95% CI, 95% confidence interval. Estimates shown in bold type are significant at P<0.05. |
| d: The interaction effect between country and wave examines changes over time in key appeal, salience and harm perception-related outcome measures, comparing England (which introduced standardized packaging regulations and larger pictorial HWLs) with the six European countries that each introduced larger pictorial HWLs only. The weighted estimates, shown above, control for gender, age, household income, education, wave of recruitment, nicotine dependence (HSI) and past-year quit attempts. |

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